UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,417	03/01/2004	Charles A. Mesko	MESK-30	1471

26875 7590 09/24/2009

WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,417	MESKO, CHARLES A.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,5,9-17,19,24,27,28,30,33 and 36-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,5,9-17,19,24,27,28,30,33 and 36-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/10/09 has been entered.

2. Applicant's arguments filed 8/10/09 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 4-5, 9-17, 19, 24, 27-28, 30, 33 and 36-62 are pending in this office action.

5. The rejection of claims 7, 19 and 36 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment and/ or cancellation of the claims.

6. The rejection of claim 17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn due to the amendment of the claims.

7. The rejection of claims 4-5, 7-11, 12-19, 22, 24, 27-28, 30, 33 and 36 under 35 U.S.C. 103(a) as being unpatentable over Garfield et al., (US 5,595,970) and Ang et al. (2001) and Chwalisz et al., (US 5,906,987) and Coral-Cure www.coral-cure.com/mens-health in view of Chen et al. (2002) and Chiou et al. (2001) is withdrawn due to Applicant's arguments concerning Garfield does not teach coumarin as the second ingredient effective to stimulate the production of cGMP and that Garfield also fails to teach *Eurycoma longifolia Jack.*

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-5, 9, 13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sambandan et al. (US 7,132,117) in view of Di Rosa et al (WO 95/00142).

Sambandan et al teach a pharmaceutical composition comprising *Eurycoma longifolia* (i.e., *Eurycoma longifolia jack)* in a pharmaceutically acceptable carrier (thus pharmaceutical composition; see col. 4, lines 50-65) that may be topically applied in the form of cream, gel, ointment and/or lotion (as required by instant claim 4; see col. 5, lines 40-45). Sambandan further teaches *Eurycoma longifolia jack* with a dosage range of about 0.01mg/kg to 200 mg/kg, which meets the limitation of instant claim 5 (see col. 6, lines 23-25). With the instant limitation of claim 24, the composition in the form of a gel, lotion, etc intrinsically will transport the active agent (i.e., *Eurycoma longifolia)* to the internal site for treatment.

However, Sambandan et al. fails to teach the composition comprises coumarin.

Di Rosa teach a pharmaceutical composition comprising coumarin (as 8-chloro-3-(beta-diethylaminoethyl)- 4-methyl-7-ethoxycarbonyl-methyl coumarin) for topical administration as a cream (see example 5, page 35 as required by instant claims 4 and 33). The intended use to be effective to stimulate cGMP is intrinsically met because coumarin is involved in release of nitric oxide (i.e., stimulates the production of nitric oxide) which is known in the art to stimulate cGMP (see also page 3, lines 30-35) as required by instant claim 9.

Di Rosa further teaches the inhibition of NO synthase by coumarin (as it relates to claim 13; see page 8, lines 10-11). With the instant limitation of claims 24 and 33,

the composition in the form of a gel, lotion, etc intrinsically will transport the active agent (i.e., coumarin) to the internal site for treatment.

One of ordinary skill in the art would have been motivated to include Di Rosa's coumarin in the pharmaceutical formulation of Sambandan because Di Rosa teaches coumarin is used for treating vasodilation of tissue damage (i.e., inclusive of sexual dysfunction or erectile dysfunction; see page 3, lines 9-11), and because the pharmaceutical composition of Sambandan for treating sexual dysfunction in males reasonably could also include a second ingredient, such as coumarin, which Di Rosa teaches can also be used to treat sexual dysfunction in a male. Accordingly, In re Kerkhoven, 205 USPQ 1069 (CCPA 1980), the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant process claims, given the teaching of the prior art methods of using *Eurycoma longifolia jack* and coumarin individually for treating vasodilation of tissue damage/sexual dysfunction, it would have been obvious to use both compounds for the treatment of sexual dysfunction in a male with the combined compounds because the idea of doing so would have logically followed from their having been individually taught in the prior art to be useful as therapeutic agents.

9. Claims 4-5, 7-11, 12-19, 22, 24, 27-28, 30, 33 and 36-62 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sambandan et al. (US 7,132,117) in view of Di Rosa et al. (WO 95/00142).

Sambandan is applied here as above. The limitations of the formulation adapted to be administered topically are applied here as above, as it relates to claims 37, 45 and 60.

However Sambandan fails to teach coumarin as osthole, nor teach using Cnidium monnier and also fails to teach the limitations in claims 13-17, 19, 27-28, 30, 33, 36, 37-61.

Di Rosa is applied here as above.

However Di Rosa fails to teach that coumarin as osthole, nor does Di Rosa teach Cnidium monnier and further fails to teach the limitations in claims 13-17, 19, 27-28, 30, 36, 37-61.

Coral-cure teaches a homeopathic form 10X topical formulation comprising testosterone (i.e., a growth hormone, and a composition which potentiates/stimulates hormones), and Tribulus L. Terrestris (as it relates to claims 37-40, 52-53, 55). Coral-cure also teaches the formulation including plurality of inactive ingredients such as saw palmetto extract for the use of overall prostate health (see pg 4, 3rd para from bottom as required by instant claims 30, 43-44, 58-59). Coral-cure also teaches the active homeopathic ingredient is Mucana Pruriens (as required by claims 28, 39-40, 46-50 and 52-55). Therefore it is reasonable to consider Mucana Pruriens and Tribulus L.

Terrestris as elements for synthesizing a catecholamine, as required by instant claims 37 and 46-53, because they otherwise structurally meet the limitations of these claims.

However Coral-cure fails to teach the formulation as having first ingredient – coumarin and also fails to teach Cnidium monier, nor does it teach the enzymes is phosphodiesterase (as required by instant claims 13-15). Coral-cure also fails to teach Epimedium Sagittatum (as required by instant claims 17 and 19).

Bulk nutrition is introduced for its teaching of Cnidium extract (i.e., Cnidium monier).

Bulk Nutrition teaches a composition comprising L-arginine, Cnidium extract. It is known to one of ordinary skill that L-arginine increases natural production of nitric oxide and that Cnidium Monnier increases nitric oxide release and inhibits PDE-5 (as taught in the specification on pg 10, lines 4-9 of the instant specification when using the specification as a dictionary; as required by instant claims 11, 13-16, 33 and 36). The composition also includes a stimulant for blood flow, such as Epimedium sagittatum (as required by instant claims 17 and 61). Also it is known that coumarins are from Cnidium Monnier. Thus administering Cnidium Monnier is the same as administering coumarin which is further the same as administering osthole. Therefore the limitations of claims 10-11 are met, as evidenced by Chiou et al. (see abstract, page 282). With regards to the dosage amounts of Cnidium monnier and Epimedium sagittatum, it is reasonable to conclude that in a 650 mg blend there is at least 0.02 mg present. Therefore 0.02x70 kg (weight of a standard human) equals 140 mg of each present.

Based on the teaching and the target treatment one of ordinary skill in the art would be motivated to add other active natural ingredients that would act synergistically in producing the end targeted result. One of ordinary skill in the art would have been motivated to formulate a pharmaceutical formulation by combining the pharmaceutical composition taught by Sambandan for treating sexual dysfunction with Di Rosa teaching of coumarin for treating vasodilation of tissue damage to further include Coral-cure's teachings of a 10X homeopathic cream for producing sexual stimulation and Bulk Nutrition's teaching to effectively treat sexual dysfunction in a human

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
9/16/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649